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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,612	09/18/2002	Jean-Francois Bonello	0512-1030	2604

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,612	Applicant(s) BONELLO ET AL	
	Examiner Cynthia Collins	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-19 and 21-35 is/are pending in the application.
- 4a) Of the above claim(s) 27-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-19 and 21-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>0805</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed August 17, 2005 has been entered.

Claims 1-16, 20 and 36-45 are cancelled.

Claims 17, 23 and 26-35 are currently amended.

Claims 27-35 are withdrawn.

Claims 17-19 and 21-35 are pending.

Claims 17-19 and 21-26 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

Information Disclosure Statement

With regard to the previously submitted IDS references that were not considered due to a failure to list the reference dates on form 1449, Applicant notes that the two publications were cited with dates in the International Search Report that was attached with the IDS. Applicant also notes that a copy of the IDS filed with the present application is attached herewith and that the revised Form PTO-1449 that reflects the appropriate publication dates of the two articles. In view of the above, Applicant requests the consideration of the two publications at this time. (reply pages 11-12)

The nonpatent publications are not considered because neither the original nor the revised Form PTO-1449 reflects the appropriate publication dates of two of the nonpatent publications listed, and because neither the original nor the revised Form PTO-1449 reflects the place of publication of any of the nonpatent publications listed, as required by

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37 CFR 1.98 ("Each publication listed in an information disclosure statement must be identified by publisher, author (if any), title, relevant pages of the publication, date, and place of publication.").

Claim Rejections - 35 USC § 112

Claim 24 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the office action mailed May 17, 2005.

Applicant's argument filed August 17, 2005 has been fully considered but is not persuasive.

Applicant argues that claim 24 has been amended in a manner so as to obviate this rejection (reply page 12).

Applicant's argument is not persuasive because claim 24 is as previously presented, i.e. claim 24 has not been amended. It is suggested that the definite article "the" (before the phrase "fatty acids") be deleted in order to overcome the rejection.

Claims 17-19 and 21-22 remain rejected, and claims 23-26 are rejected, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the

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time the application was filed, had possession of the claimed invention, for the reasons of record set forth in the office action mailed May 17, 2005.

Applicant's arguments filed August 17, 2005 have been fully considered but they are not persuasive.

Applicant points to the amendment of the claims to recite the promoter sequence comprises SEQ ID NO:2 or a sequence at least 80% identical to SEQ ID NO: 2, wherein the sequence at least 80% identical to SEQ ID NO: 2 comprises a consensus sequence SEQ ID NO:7. Applicant also points out that the specification at page 15 indicates that a highly preserved sequence of 265 base pairs (SEQ ID NO:7) contains all the cis information necessary for an expression of specific genes in the region surrounding the embryo. Applicant maintains that the presence of SEQ ID NO:7 and the claimed promoter sequence is believed to be sufficient to drive gene expression specifically in embryo and seeds and at an earlier stage of development of the endosperm, and that thus one of ordinary skill the would recognize that applicants were possession application. Applicant maintains that since the claims recite that the structure of the promoter sequence comprises SEQ ID NO:2 or a sequence at least 80% identical to SEQ ID NO: 2, wherein the sequence at least 80% identical to SEQ ID NO: 2 comprises a consensus sequence SEQ ID NO:7, the claims as amended show Applicant's possession of the claimed invention at the time the application was filed. (reply pages 13-15)

The Examiner maintains that the claimed invention is not adequately described, as a showing of possession alone is not sufficient to satisfy the written description requirement. See *Enzo Biochem Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1609, 1617:

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Application of the written description requirement, however, is not subsumed by the "possession" inquiry. A showing of "possession" is ancillary to the *statutory* mandate that "[t]he specification shall contain a written description of the invention," and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention. After all, as indicated above, one can show possession of an invention by means of an affidavit or declaration during prosecution, as one does in an interference or when one files an affidavit under 37 C.F.R. § 1.131 to antedate a reference. However, such a showing of possession alone does not cure the lack of a written description in the specification, as required by statute.

In the instant case the description of a single promoter nucleotide sequence of SEQ ID NO:2 does not adequately describe the claimed genus of promoter sequences which encompasses numerous undisclosed and/or uncharacterized variants of SEQ ID NO:2 that are 80% identical to SEQ ID NO:2 and that comprise a consensus sequence of SEQ ID NO:7.

Claims 17-19 and 21-22 remain rejected, and claims 23-26 are rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the nucleic acid of SEQ ID No. 2, does not reasonably provide enablement for promoter sequences that are at least 80% identical to SEQ ID No.2 and that comprise a consensus sequence of SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, for the reasons of record set forth in the office action mailed May 17, 2005.

Applicant's arguments filed August 17, 2005 have been fully considered but they are not persuasive.

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Applicant believes the objection is obviated in view of the amendment of claims 17-22 which recites that the sequence at least 80% identical to SEQ ID NO: 2 comprises the consensus sequence SEQ ID NO: 7 (reply page 15).

The Examiner maintains that the full scope of the claimed invention is not enabled. In the instant case the disclosure of a single promoter nucleotide sequence of SEQ ID NO:2 does not provide sufficient guidance for one skilled in the art to discriminate between sequence variants that meet the functional requirements of the claims and sequence variants that do not. Such guidance is necessary because the specific functional attributes of a variant promoter sequence cannot be predicted on the basis of the presence of a consensus sequence, since the specific functional effect of a consensus sequence in a promoter may vary depending on its context.

See, for example, Fiedler U. et al. (A complex ensemble of cis-regulatory elements controls the expression of a *Vicia faba* non-storage seed protein gene. Plant Mol Biol. 1993 Jul;22(4):669-79), who teach that an RY consensus sequence "CATGCATG" acts as a negative transcriptional regulatory element in the seed-specific promoter of the *Vicia faba* non-storage seed protein gene, and as a positive transcriptional regulatory element in seed-specific promoters obtained from other plant structural genes (page 677 paragraph spanning columns 1 and 2).

Absent guidance with respect to which of the claimed variant sequences would have the desired functional attributes and which would not, one skilled in the art would have to synthesize and/or isolate from undisclosed sources numerous different sequences meeting the structural limitations set forth in the claims, and then test each individual sequence for its ability to express an operatively linked coding sequence in the region of

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an endosperm surrounding an embryo in seed and intervening in the early stages of endosperm development, in order to discriminate between operative and inoperative embodiments encompassed by the claims. Such a trial and error approach to practicing the claimed invention would constitute undue experimentation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on (571) 272-0745. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Primary Examiner
Art Unit 1638

CC


10/14/05